IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., MERZ PHARMA GMBH & CO. KGAA, MERZ PHARMACEUTICALS GMBH, and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., WOCKHARDT USA LLC, WOCKHARDT BIO AG, WOCKHARDT LTD., SUN PHARMA GLOBAL FZE, and SUN PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	C.A. No. 14-121 (LPS)
FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. APOTEX CORP., APOTEX INC., ZYDUS PHARMACEUTICALS (USA), INC., CADILA HEALTHCARE LTD. (d/b/a/ ZYDUS CADILA), PAR PHARMACEUTICAL, INC., ANCHEN PHARMACEUTICALS, INC. and WATSON LABORATORIES, INC. – FLORIDA, Defendants.	C.A. No. 14-200 (LPS)

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., MERZ PHARMA GMBH & CO. KGAA, MERZ PHARMACEUTICALS GMBH, and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMERIGEN PHARMACEUTICALS, INC., AMERIGEN PHARMACEUTICALS LTD. and MYLAN PHARMACEUTICALS INC., Defendants.	)	C.A. No. 14-508 (LPS)
FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. RANBAXY INC., RANBAXY LABORATORIES LIMITED, and TEVA PHARMACEUTICALS USA, INC.., Defendants.	)	C.A. No. 14-686 (LPS)

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., ANCHEN PHARMACEUTICALS, INC., AMERIGEN PHARMACEUTICALS, INC., and AMERIGEN PHARMACEUTICALS LTD., Defendants.	Civil Action No. 14-1058 (LPS)
FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. AMERIGEN PHARMACEUTICALS, INC., and AMERIGEN PHARMACEUTICALS LTD., Defendants.	Civil Action No. 14-1271 (LPS)

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

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I. NATURE AND STAGE OF THE PROCEEDINGS

This is a Hatch-Waxman case regarding the patents protecting Namenda XR®, an important drug for the treatment of Alzheimer's disease. Pursuant to the schedule set by the Court, Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd. (collectively, "Forest"), Merz Pharma GmbH & Co. KGaA, Merz Pharmaceuticals GmbH, and Adamas Pharmaceuticals, Inc. (collectively, "Plaintiffs") respectfully submit this Opening Claim Construction Brief in support of their proposed claim constructions.

II. SUMMARY OF THE ARGUMENT

Plaintiffs' proposed constructions are simple, straightforward, and grounded firmly in the intrinsic evidence. Indeed, most of the disputed terms require no construction beyond the plain meaning, as set forth in Plaintiffs' proposed constructions. For one term, the specification provides an express definition, which Plaintiffs adopt as their proposed construction.

Defendants' proposed constructions, on the other hand, seek to narrow the claims by improperly reading in numerous limitations. Contrary to fundamental principles of claim construction, Defendants seek to rewrite several disputed terms in an effort to avoid infringement of the asserted claims. At the same time, Defendants disagree among themselves as to whether additional limitations should be read into the claims, confirming that Defendants' proposed constructions deviate from both plain meaning and the intrinsic evidence. Finally, Defendants object to the construction of one disputed term that has been expressly defined in the specification, and instead, purport to rely on a "plain meaning" construction that they do not identify or explain.

When not rewriting the claims, Defendants baselessly argue that they are indefinite. Indeed, Defendants improperly assert indefiniteness for six of the seven patents-in-suit as a fallback to their flawed constructions. According to Defendants, the claims must be read to

include numerous extraneous limitations, such that Defendants' accused products will not infringe, or the claims are allegedly invalid as "indefinite." But Defendants fail to apply the correct legal standard. As the United States Supreme Court recently held, a claim is definite if it informs, with reasonable certainty, those skilled in the art about the scope of the invention when read in light of the specification and prosecution history. *Nautilus, Inc. v. Biosig Instruments, Inc*., 134 S. Ct. 2120, 2124 (2014). Here, the disputed claim terms readily meet this standard, and Defendants' contentions on indefiniteness should be rejected along with their alternative – and inconsistent – constructions of the claims.

For all these reasons, as explained in more detail below, Plaintiffs respectfully request that the Court adopt their proposed constructions and reject Defendants' proposed constructions.

III. LEGAL STANDARDS FOR CLAIM CONSTRUCTION

Claims are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history. *See, e.g., Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365-67 (Fed. Cir. 2012). Intrinsic evidence (the patent claims, specification, and prosecution history) takes priority over extrinsic evidence (dictionaries, learned treatises, expert testimony) in the claim construction analysis. *Phillips v. AWH Corp*., 415 F.3d 1303, 1317 (Fed. Cir. 2005) (*en banc*).

There are two exceptions to the claim construction principle that "[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner*, 669 F.3d at 1365. The two exceptions are: (1) where an inventor has acted as a lexicographer and expressly defined a term in the specification; and (2) where an inventor has disclaimed or disavowed claim scope in the specification. *Id*. When patentee acts as a lexicographer and explains in the specification a claim term "without ambiguity or incompleteness," the definition

in the specification governs and "there is no need to search further for the meaning of the term." *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1138 (Fed. Cir. 2007).

In addition to the specification, courts rely on the prosecution history to provide "evidence of how the PTO and the inventor understood the patent" because the prosecution history "was created by the patentee in attempting to explain and obtain the patent." *Phillips*, 415 F.3d at 1317. The prosecution history informs the meaning of the claims by "demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1352 (Fed. Cir. 2010).

Extrinsic evidence, such as expert testimony, dictionaries, and learned treatises, cannot be used to contradict the intrinsic evidence. *See Phillips*, 415 F.3d at 1317-18. Expert testimony, in particular, should be "accorded no weight" when it is contrary to the "meaning shown in the specification." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584-85 (Fed. Cir. 1996). Reliance on expert testimony to contradict a claim term that is clearly and unambiguously defined in the specification is improper. *Id.*; *see also SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1210 (Fed. Cir. 2013).

IV. FACTUAL BACKGROUND

This case arises from Defendants' infringement of eight United States patents: U.S. Patent Nos. 8,168,209, 8,173,708, 8,283,379, 8,329,752, 8,362,085, and 8,598,233 (collectively, "the Went patents"); U.S. Patent No. 8,039,009 ("the '009 patent"); and U.S. Patent No. 5,061,703 ("the '703 patent"). The claims of the '703 patent are not at issue with respect to claim construction.[1]

[1] The '703 patent is asserted against one Defendant – Mylan Pharmaceuticals, Inc. ("Mylan"). The '703 patent was the subject of earlier litigation in this Court, which included

Forest holds New Drug Application ("NDA") No. 22-525 for memantine hydrochloride extended release capsules, which are marketed in the United States under the brand name Namenda XR®. (D.I. 1 at ¶ 29.)[2] Namenda XR® is approved by the United States Food and Drug Administration ("FDA") for the treatment of moderate to severe dementia of the Alzheimer's type. (Wilson Decl., Tab A at 1.)[3] The patents-in-suit are all listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") as covering Namenda XR®. (D.I. 1 at ¶ 29). Defendants have submitted Abbreviated New Drug Applications ("ANDAs") seeking approval to commercially manufacture and sell generic versions of Namenda XR® prior to the expiration of the Orange Book-listed patents.

Forest also markets and sells an immediate release form of memantine hydrochloride under the brand name Namenda®. (Wilson Decl., Tab B at 1, 18). Like Namenda XR®, immediate release Namenda® is also approved by the FDA for the treatment of moderate to severe dementia of the Alzheimer's type. (*Id.* at 1, 18).

V. U.S. PATENT NOS. 8,168,209, 8,173,708, 8,283,379, 8,329,752, 8,362,085, 8,598,233

The six Went patents are related. The '209, '708, '752, '085, and '233 patents share the same specification and claim priority to U.S. Provisional Application Nos. 60/630,885, 60/635,365, 60/701,857, and 60/669,290, filed on November 23, 2004, December 10, 2004, July 22, 2005, and April 6, 2005, respectively. (Ex. A-2, A-3, A-5, A-6, A-7).[4] The '379 patent claims priority to U.S. Provisional Application No. 60/669,290, and includes corresponding

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rulings on claim construction. *See* D.I. 373 and D.I. 426, *Forest v. Lupin, et al.*, C.A. No. 08-21-LPS (D. Del.). Mylan has not challenged the Court's construction of the '703 claims.

[2] Citations to the record refer to C.A. No. 14-121-LPS.

[3] "Wilson Decl., Tab __" refers to exhibits attached to the Declaration of Robert B. Wilson, filed concurrently with this brief.

[4] "Ex. __" refers to exhibits attached to the Appendix to the Joint Claim Construction Chart ("Joint Appendix"), submitted on March 11, 2015. (D.I. 81-84).

disclosures to the other Went patents. (Ex. A-4). The Went patents are assigned to Plaintiff Adamas Pharmaceuticals, Inc. and exclusively licensed to Forest. (D.I. 1 at ¶¶ 25-30).

A. The Specification

The first-to-issue Went patent, the '209 patent, issued on May 1, 2012 from an application filed on July 30, 2009. (Ex. A-2). The '209 patent is titled "Method and Composition for Administering an NMDA Receptor Antagonist to a Subject." (*Id.*).

The Went patents disclose pharmaceutical compositions and methods for administering a class of compounds called N-methyl-D-Aspartate receptor (NMDAr) antagonists. (1:23-25).[5] The Went patents explain that NMDAr antagonists are useful for the treatment of Alzheimer's disease. (16:14-34, 17:8-17). Memantine hydrochloride, the active ingredient in Namenda XR®, is an NMDAr antagonist. (2:53-58; 8:36-38).

In the Background of the Invention, the Went patents describe several drawbacks of immediate release formulations of NMDAr antagonists. Ideally, NMDAr antagonists should be present at "a concentration sufficient to reduce the symptoms or damaging effects of the disease in the absence of debilitating side effects." (1:60-63). In immediate release dosage forms, however, these drugs, "need to be administered frequently." (1:63-67). This leads "to difficulty in achieving adequate patient compliance" with the required dosing regimen. (1:67-2:4).

The pharmaceutical compositions and methods disclosed in the Went patents include an NMDAr antagonist that is formulated in an "extended" or "sustained" release form, with or without an immediate release component. (2:34-38, 7:49-51, 13:45-47).[6] The compositions and methods of the invention provide a concentration of the drug over a desired time period that is

[5] Citations to the specification are from the '209 patent. (Joint Appendix at Ex. A-2).

[6] The Went patents generally use the terms "extended release" and "sustained release" to describe the formulations of the invention. (*See, e.g.*, 2:34-45, 3:22-24, 6:58-7:37, 7:49-54).

"high enough to be therapeutically effective" but released at a rate that is low enough so as "to avoid adverse events associated with the NMDAr antagonist." (7:51-54; *see also* 2:10-15, 2:34-38). "Therapeutic levels are therefore achieved while minimizing debilitating side-effects that are usually associated with immediate release formulations." (7:57-59; *see also* 14:33-37).

The compositions and methods of the invention also "enable a reduction in the dosing frequency" compared to immediate release forms. (2:15-19; *see also* 14:37-41). For example, an NMDAr antagonist ordinarily administered two times per day when dosed in an immediate release form may be provided to the subject once per day using the formulations in the Went patents, thereby "improving patient compliance and caregiver convenience." (2:15-19, *see also* 4:47-53, 7:59-65, 17:25-31).

Finally, by providing a more constant amount of drug to the subject being treated over a given period of time, the compositions and methods disclosed in the Went patents "allow for higher doses of NMDAr antagonist to be safely administered." (2:28-31; *see also* 14:37-41, 17:19-24). Thus, the compositions and methods of the Went patents enable "increased dosages" of drug to be administered "for appropriate indications." (8:3-7).

B. The Asserted Claims

Pursuant to the limits set by the Scheduling Order, Plaintiffs asserted a total of 48 claims in their Preliminary Infringement Contentions. (*See* D.I. 61 at ¶ 14). The asserted claims of the Went patents are listed below:

- '209 patent: claims 1, 2, 3, 4, 6, 10, 11, 12, 13, 14
- '708 patent: claims 1, 3, 4, 5, 6, 8, 9, 10, 12, 13, 14, 15, 17, 18
- '379 patent: claims 1, 3, 5
- '752 patent: claims 1, 7, 9, 15
- '085 patent: claims 1, 5, 7, 11
- '233 patent: claims 1, 3, 4, 8

The asserted claims of the Went patents are directed to pharmaceutical compositions and

methods of treatment using extended release formulations of memantine or a pharmaceutically acceptable salt of memantine, such as memantine hydrochloride. The claims recite certain pharmacokinetic properties of the claimed compositions that provide the advantages described in the specification for the extended release compositions of the invention over immediate release compositions. Claim 1 of the '209 patent is representative:

> A solid pharmaceutical composition in a unit dosage form for once daily oral administration comprising
>
> an extended release formulation of 5 to 40 mg memantine or pharmaceutically acceptable salt thereof,
>
> wherein administration of a dose of the composition to a human subject provides a **plasma memantine concentration profile**, as measured in a **single-dose human PK study**,
>
> characterized by a **change in memantine concentration as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form** comprising the same dose of memantine as the composition,
>
> wherein the **dC/dT is measured between the time period of 0 to Tmax** of the immediate release form of memantine.

(Ex. A-2 at 37:11-22, emphasis added). Disputed terms in claim 1 are shown in bold/underline.

Claim 1 is generally directed to a unit oral dosage form that is administered once daily. The composition comprises 5 to 40 mg of memantine in an extended release formulation. The claim describes the pharmacokinetic properties of the claimed extended release formulation when the composition is administered to a human subject. Specifically, the claim recites the "change in memantine concentration" measured in the plasma (*i.e.*, the liquid portion of the blood) of the subject "as a function of time." This is abbreviated "dC/dT." (*See* 4:24-28, 4:36-38). Claim 1 provides that the claimed composition has a dC/dT that is less than 50% of an immediate release dosage form having the same amount of memantine. In other words, the rate of increase in memantine concentration following administration of the claimed composition is less than half (50%) of the rate of increase in memantine concentration from the immediate

release dosage form. (*See* 4:39-50). This difference in the rate of increase in concentration between the claimed composition and the immediate release dosage form is observed in the time period after administration of the claimed composition – which is defined in claim 1 as the time period from 0 hours to Tmax of the immediate release dosage form.[7] By reducing the initial rate of increase in memantine concentration in the bloodstream, the claimed composition provides the benefits described in the Went specification as to side-effects, dosing frequency, and dosage amount, compared to an immediate release formulation. (*See* 7:49-8:7).

C. The Pertinent Art and the Person of Ordinary Skill in the Art

The pertinent art for the Went patents, as reflected in the specification and claims, is the field of pharmaceutical formulation. (*See* 1:23-25). The person of ordinary skill in the art of the Went patents as of the date of invention for each of the asserted claims would have been capable of preparing routine pharmaceutical formulations and would have had either: (1) a Master's degree in biochemistry, chemistry, pharmaceutical sciences, pharmacy, or a related field, and two or more years of practical experience in those areas; or (2) a Bachelor's degree in biochemistry, chemistry, pharmaceutical sciences, pharmacy, or a related field, and three or more years of practical experience in those areas. In addition, a person of ordinary skill in the art of the Went patents as of the date of invention of each of the asserted claims would have had a basic understanding of, and practical experience preparing and/or designing, immediate release and modified release solid oral dosage formulations.

D. The Disputed Claim Terms

The disputed terms in the asserted claims of the Went patents are discussed below. The parties' proposed constructions are shown side-by-side in the tables for reference.

[7] "Tmax" is a pharmacokinetic parameter that refers to the time required to reach the maximum concentration ("Cmax") of active ingredient in the bloodstream. (4:34-36).

1. "immediate release form of memantine"

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
'209: 1 '708: 1, 6, 10, 15 '379: 1 '752: 1, 9 '085: 1, 7 '233: 1	immediate release form of memantine	the present commercially available 5 mg and 10 mg tablets (i.e., Namenda from Forest Laboratories, Inc. or formulations having substantially the same release profiles as Namenda)	plain meaning; no construction necessary

This term is expressly defined in the specification. (3:14-18). The definition refers to the commercially available form of immediate release memantine, Namenda®, and formulations having substantially the same release profiles as Namenda®. (*Id*.) Plaintiffs' proposed construction quotes this express definition ***exactly***.

The specification leaves no room for doubt. The specification states that "[a]s used herein, the immediate release (IR) formulation for memantine ***means*** the present commercially available 5 mg and 10 mg tablets (i.e., Namenda from Forest Laboratories, Inc. or formulations having substantially the same release profiles as Namenda)." (*Id*., emphasis added). This is a prime example of the patentee acting as a lexicographer to define a particular claim term. *See Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mut. Pharm. Co.*, 384 F.3d 1333, 1339-40 (Fed. Cir. 2004) (expressly defining "solubilizer" to mean surface active agents). As such, this express definition controls.[8]

Defendants, by contrast, ignore the express definition in the specification, and instead, propose a construction that refers to "plain meaning; no construction necessary" without

[8] Consistent with the express definition, the Went patents identify Namenda® throughout the specification as the immediate release formulation to which the claimed modified release compositions are compared. (*See, e.g*., 4:39-47, 6:58-7:11, 7:26-32, 14:42-15:9, Figures 1A, 1B, 2D, Examples 16, 24).

identifying what they contend the plain meaning should be or how the plain meaning allegedly differs from the express definition in the specification. Defendants' proposal is meritless. Indeed, contrary to their contentions here, Defendants relied on the specification definition as the meaning of this term in their Revised Preliminary Invalidity Contentions, served on January 23, 2015. (Wilson Decl., Tab C at 64).

Plaintiffs' proposed construction should be adopted, as it is taken ***verbatim*** from the express definition recited in the specification. (3:14-18); *see, e.g.*, *Sinorgchem*, 511 F.3d at 1138 (finding that when patentee acts as a lexicographer, defining a term in the specification "without ambiguity or incompleteness," there "is no need to search further for the meaning of the term").

2. "plasma memantine concentration profile"

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
'209: 1	plasma memantine concentration profile	plain meaning; no construction necessary; or plasma memantine concentration profile	*mean* plasma memantine concentration profile[9]

The parties appear to agree that the words "plasma memantine concentration profile" need no construction. Notably, Defendants do not attempt to construe these words in the claim. Defendants do, however, seek to insert the word "mean" at the front of this term. Consistent with its plain meaning to a person of ordinary skill, "plasma" refers to the liquid fraction of a blood sample taken from a subject. (*See* Example 19 ("Blood Collection")). The specification also explains that "concentration" refers to the amount of an active pharmaceutical ingredient in a biological sample, such as a patient sample (*e.g.*, blood, serum, or cerebrospinal fluid). (4:24-

[9] Portions of Defendants' proposed constructions that have been read into the disputed claim terms are highlighted in underline/italics throughout.

28). The term "plasma memantine concentration profile" refers to the concentration of the memantine active ingredient in the plasma of a subject measured over time. The Went patents illustrate plasma memantine concentration profiles in Figures 1A, 1B, and 2D, and describe those graphs as "showing the memantine plasma concentration" over a period of hours or days. (6:58-7:11, 7:26-32; *see also* Example 16).

Defendants seek to read the additional word "mean" into this term. Here, "mean" presumably refers to an average plasma memantine concentration profile calculated from individual profiles measured in a group of subjects. But the express language of the claims in the Went patents demonstrates that this term should not be so limited. The claims of the '752, '085, and '233 patents expressly recite "mean" plasma memantine concentration profile. (*See, e.g.*, Ex. A-5, claims 1, 9; Ex. A-6, claims 1, 7; Ex. A-7, claim 1). The claims of the '209, '708, and '379 patents do not. (*See, e.g.*, Ex. A-2, claim 1; Ex. A-3, claims 1, 6, 10, 15; Ex. A-4, claim 1). Thus, when the inventors intended to claim "mean" plasma memantine concentration profiles, they expressly did so. And when they did not intend the claims to be so limited, they did not use the term "mean." Defendants' proposed construction adds the word "mean" to every asserted claim, thereby rendering the term superfluous in those claims where "mean" is expressly recited. *See, e.g.*, *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1361-62 (Fed. Cir. 2007) (rejecting a construction that rendered portions of a claim superfluous). In addition, Defendants' proposed construction violates the claim construction principle that claims using different words should be accorded different meanings. *See, e.g.*, *Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1367-71 (Fed. Cir. 2012). Accordingly, Defendants' proposed construction should be rejected.

3. "change in memantine concentration as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the composition"

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
'209: 1 '708: 1, 6 '752: 1 '085: 1	change in memantine concentration as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the composition[10]	plain meaning; no construction necessary; or change in plasma memantine concentration of the extended [sustained] release composition as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the extended release composition	Indefinite Alternatively, if the Court determines this term is amenable to construction: change in *mean* plasma concentration of memantine as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the extended release composition, *where the plasma concentration of the extended release and the immediate release memantine are measured in the same PK study conducted in human subjects*

This term relates to the pharmacokinetic parameter termed "dC/dT" in the Went patents. The specification expressly defines dC/dT as the "change in the concentration" of an active pharmaceutical ingredient in a biological sample "over a prescribed time." (4:24-38). The asserted claims reiterate this express definition by referring to dC/dT as the "change in memantine concentration as a function of time." (*See, e.g.*, '209 patent, claim 1). Graphically, dC/dT is a measure of the rate of change of the concentration of the memantine active ingredient along the plasma concentration curve. (*See* Figures 1A, 2D). In other words, dC/dT is a

[10] The language cited for this term is from claim 1 of the '209 patent. (*See* Ex. A-2 at 37:17-20). Variations in the language of this term in the asserted claims do not change Plaintiffs' contentions regarding the proper construction. Plaintiffs note, however, that the corresponding terms in the asserted claims of the '708, 752, and '085 patents recite "less than ***about*** 50%." (*See* Ex. A-3, claims 1, 6; Ex. A-5, claim 1; Ex. A-6, claim 1, emphasis added).

measure of how quickly the memantine concentration is going up, or going down, over a specified time period. (*Id*.).

The disputed term compares the dC/dT of the extended release composition of the invention with the dC/dT of an immediate release dosage form having the same amount of memantine as the extended release composition. Specifically, this term provides that the dC/dT of the extended release composition is less than 50% of the same dose of an immediate release formulation – *i.e*., the slope of the plasma concentration curve over time is not as steep. (*See* 5:8-13, 13:58-63, Figures 1A, 2D). As the specification explains, by lowering the dC/dT as compared to an immediate release dosage form, the compositions of the invention "enable the use of higher doses" of memantine, with "equal or fewer adverse effects than observed for IR formulations." (5:56-6:3; *see also* 7:49-54, 14:30-41).

Defendants contend, without explanation, that this term is indefinite. In the alternative, Defendants propose a construction that reads in additional requirements that do not appear in this claim term. First, Defendants read in the term "mean" plasma concentration into claims that are not so limited. As discussed above, the inventors expressly claimed "mean" plasma concentration in some asserted claims and not others. There is no reason to incorporate that term into claims where it is not expressly recited.

Second, there is a split among Defendants about whether this term requires the plasma memantine concentration for the modified release composition and the immediate release composition to be "measured in ***the same*** PK study conducted in human subjects."[11] The claims

[11] In the Joint Claim Construction Chart, Ranbaxy and Lupin dissent from the other Defendants and indicate that they "take no position on whether the quoted claim language requires that the sustained release dosage form and the immediate release dosage form be tested in 'the same PK study,' and thus do not join in the portion of this proposed construction setting forth that requirement." (D.I. 80, Exhibit C at 4 n.13).

do not include this requirement; the proposed insertion of this limitation is merely an attempt – by certain Defendants – to rewrite this portion of the asserted claims. Under Defendants' proposed construction, every extended release formulation must be tested side by side with an immediate release form in the same study before any determination regarding infringement may be made. That construction is unduly restrictive, particularly where, as here, there is nothing in the claim language, specification, or prosecution history that remotely suggests the inventors intended to so limit the claims. The standard for finding any such disavowal is "exacting." *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371-74 (Fed. Cir. 2014). The patentee must demonstrate "a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Id*. No such disavowal occurred here. Instead, Defendants are attempting to avoid infringement by proposing an unduly narrow construction of this disputed term, without basis in the intrinsic evidence.

4. "the dC/dT is measured between the time period of 0 to Tmax of the immediate release form of memantine"

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
'209: 1 '708: 1, 6 '752: 1 '085: 1	the dC/dT is measured between the time period of 0 to Tmax of the immediate release form of memantine[12]	plain meaning; no construction necessary; or the dC/dT is measured between the time period of 0 to Tmax of the immediate release form of memantine	*the dC/dT for the immediate release formulation is the mean maximum plasma memantine concentration (Cmax) of the immediate release formulation divided by the Tmax of immediate release formulation and the dC/dT for the extended release formulation is mean plasma memantine concentration of the extended release formulation at time of Tmax of the immediate release*

[12] The language cited for this term is from claim 1 of the '209 patent. (*See* Ex. A-2 at 37:21-22).

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
			formulation divided by the Tmax of the immediate release formulation

This term defines the time period over which the dC/dT of the extended release composition is measured. For these asserted claims, the time period is 0 hours to Tmax of the immediate release formulation.[13] Thus, according to its plain meaning, this term defines the time period over which the dC/dT of the extended release composition is analyzed and compared to the dC/dT of an immediate release form of memantine.

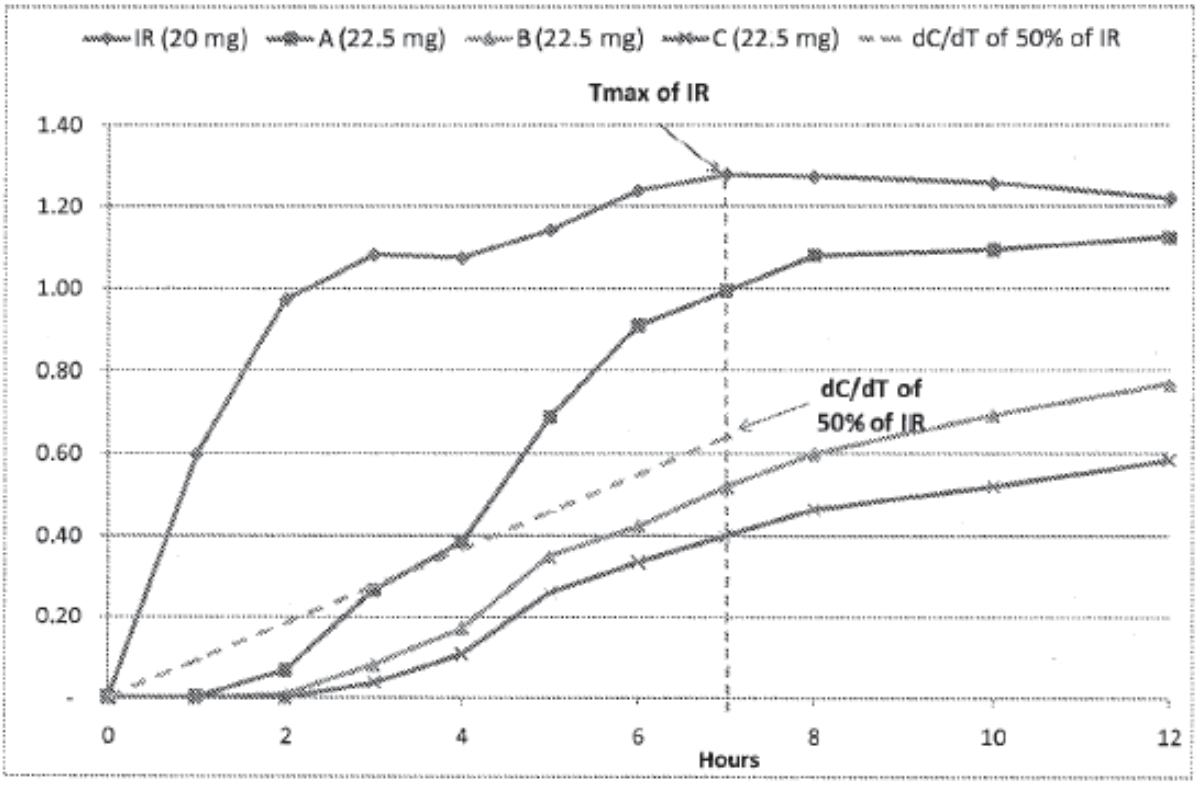
Defendants' proposed construction is a wholesale rewrite of this term that completely ignores the claim language and reads in several limitations that do not appear in the asserted claims. As before, Defendants improperly try to add "mean" to this term, regardless of whether "mean" is expressly recited in the asserted claims or not. Further, Defendants improperly try to add a specific calculation of dC/dT that is found nowhere in the asserted claims. Defendants seek to limit the analysis of dC/dT to a specific methodology, apparently in an attempt to avoid infringement. But this claim term is not so limited. The claims recite a comparison of dC/dT over a particular time period. There is no principled basis for adding further restrictions to that comparison.

Although a calculation of dC/dT may be informative of infringement, it is not required. The Declaration of Dr. Gregory Went submitted during prosecution of the '209 patent illustrates this point clearly.[14] In his Declaration, Dr. Went illustrates an analysis of dC/dT. Figure 1,

[13] As noted above, the term "Tmax" is familiar to a person of ordinary skill in the art and is defined in the specification consistent with its ordinary usage: "[t]he time required to reach the maximal concentration ('Cmax') in a particular patient sample type." (4:34-36).

[14] Citations to Went Declaration refer to Ex. B-2 at 36-43.

reproduced below, shows the plasma memantine concentration for an immediate release formulation and three extended release formulations (identified as A, B, C):



(Ex. B-2, 11/5/2010, Declaration Under 37 C.F.R. § 1.132 at 3). The immediate release concentration profile is the highest curve running across the top of the graph. Tmax for the immediate release dosage form is marked on this curve at about 7 hours. The dotted line plotted from 0 hours to Tmax represents 50% of the dC/dT for the immediate release formulation, as labeled. As Dr. Went explains in his Declaration, the plasma memantine concentration curves for extended release formulations B and C (the lowest curves in the graph) fall below the 50% line from 0 to Tmax, and therefore, satisfy the dC/dT element of the claims. (*Id.* at 4).

This graphical analysis is set forth in Declarations that Dr. Went submitted during prosecution of each of the asserted patents. (Ex. B-2, B-3, 11/5/2010, Declaration Under 37 C.F.R. § 1.132 at 3; Ex. B-4, 4/2/2012, Corrected Declaration Under 37 C.F.R. § 1.132; Ex. B-5,

B-6, B-7, 6/25/2012, Declaration Under 37 C.F.R. § 1.132 at 3). With their proposed construction, Defendants seek to exclude this graphical analysis of dC/dT and substitute a particular mathematical calculation that requires the comparison of dC/dT to be performed one way and one way only. Specifically, Defendants' proposed construction requires dC/dT to be calculated as a single value calculated at one time point. But nothing in the plain language of the asserted claims or the specification limits the term dC/dT to a single calculation. In fact, the express claim language describes dC/dT over a "time period" from 0 hours to Tmax. Defendants' proposed construction improperly renders this claim language – "between the time period of 0 to Tmax" – superfluous. *See, e.g.*, *Stumbo*, 508 F.3d at 1361-62. Indeed, Defendants highlight this flaw by excluding the express claim language from their proposed construction. As such, Defendants' proposed construction is inconsistent with the intrinsic evidence and should be rejected.

5. "change in plasma concentration as a function of time (dC/dT) in a defined time period of 0 to 6 hours after administration … that is less than about 50% of the dC/dT provided by the same quantity of an immediate release form of memantine in said defined time period"

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
'708: 10, 15 '379: 1 '752: 9 '085: 7 '233: 1	change in plasma concentration as a function of time (dC/dT) in a defined time period of 0 to 6 hours after administration … that is less than about 50% of the dC/dT provided by the same quantity of an immediate release form of memantine in said defined time period[15]	plain meaning; no construction necessary; or change in plasma memantine concentration of the sustained [extended] release dosage form as a function of time (dC/dT) in a defined time period of 0 to 6 hours after administration … that is less than about 50% of the dC/dT provided by the same quantity of an immediate	Indefinite Alternatively, if the Court determines this term is amenable to construction: *the dC/dT for the immediate release form of memantine is the mean plasma memantine concentration of the immediate release form of memantine at 6 hours after administration divided by 6 hours and the*

[15] The language cited for this term is from claim 10 of the '708 patent. (*See* Ex. A-3 at 34:38-43).

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
		release form of memantine in said defined time period	*dC/dT for the sustained release memantine is mean plasma memantine concentration of the sustained release memantine at 6 hours after administration divided by 6 hours*, where dC/dT of the sustained release memantine is less than approximately 50% of the dC/dT of an immediate release form of memantine comprising the same quantity of memantine as the sustained release memantine, *and where the plasma concentration of the extended release and the immediate release memantine are measured in the same PK study conducted in human subjects*

This term is similar to the dC/dT claim terms discussed above. As before, the dC/dT of the extended release composition is less than about 50% of the dC/dT provided by the same quantity of an immediate release form of memantine. Here, the dC/dT is evaluated over the time period 0 hours to 6 hours after administration of the extended release composition.

As before, Defendants' proposed construction seeks to read in numerous extraneous limitations, including: (1) "mean" plasma memantine concentration (for those asserted claims where "mean" is not expressly recited); (2) the "same PK study conducted in human subjects;" and (3) a calculation of dC/dT for both the extended release and immediate release forms of memantine. None of these limitations is found in the asserted claims. The extent to which Defendants are attempting to rewrite the plain language of this term is evident from the side-by-side comparison of the actual claim language and Defendants' proposed construction in the table

above. For all the reasons discussed earlier, this term should be given its plain meaning. To the extent any construction of this term is necessary, it should be construed as Plaintiffs propose.

6. "comprising an extended release formulation of 22.5 mg to 33.75 mg memantine, or a pharmaceutically acceptable salt thereof"

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
'233: 1	comprising an extended release formulation of 22.5 mg to 33.75 mg memantine, or a pharmaceutically acceptable salt thereof	plain meaning; no construction necessary; or comprising 22.5 mg to 33.75 mg memantine, or a pharmaceutically acceptable salt thereof, in an extended release formulation	comprising 22.5 mg to 33.75 mg memantine, or a pharmaceutically acceptable salt thereof, in the extended release formulation *component of the dosage form and not including any memantine in an immediate release formulation component that may be present in the same dosage form*

This term appears in claim 1 of the '233 patent. It refers to the total amount of memantine in the claimed formulation – which is specified to be in the range of 22.5 mg to 33.75 mg – and needs no construction.

Here, Defendants seek to construe the express language "extended release formulation" to mean "extended release formulation ***component***," and seek to read in the negative limitation "***not*** including any memantine in an ***immediate release formulation component***" in the same formulation. But there is no basis for these contentions. If the inventors had intended this term to refer to an extended release formulation "component," or intended to apply a negative limitation, they would have done so. They did not, and Defendants should not be allowed to rewrite the asserted claims for purposes of this litigation.

Indeed, when the inventors intended to refer to a "component" of the claimed compositions, they did so expressly. The specification uses the term "component" consistently to refer to constituent parts that make up the formulation as a whole. (*See, e.g.*, 2:34-38, 2:38-42,

2:42-49). For example, the Summary of the Invention explains that the claimed compositions "may contain immediate release, sustained or extended release, delayed release ***components***, or combinations thereof." (3:22-24, emphasis added; *see also* 2:38-42 (the term "modified release component" refers to "controlled, extended or delayed release components"); 2:42-45 (in a preferred embodiment, the composition includes "a sustained release component"); 2:46-49 (in one example, memantine is formulated "without an immediate release component")). Likewise, when the inventors wanted to distinguish between the formulation as a whole and the constituent components, they made that distinction clear. For example, the specification explains that in the claimed compositions, the active ingredient is "desireably provided in a controlled or extended release ***form***, with or without an immediate release ***component***." (2:34-36, emphasis added).

Nothing in claim 1 of the '233 patent or elsewhere in the intrinsic evidence indicates that the term "extended release formulation" refers to an extended release ***component*** in the overall composition. Thus, Defendants' proposed construction should be rejected.

VI. U.S. PATENT NO. 8,039,009

The '009 patent is titled "Modified Release Formulations of Memantine Oral Dosage Forms." (Ex. A-1). The '009 patent issued on October 18, 2011 from an application filed on June 16, 2005, and is assigned to Forest Laboratories Holdings, Ltd. (*Id*.).

A. The Specification

The '009 patent discloses pharmaceutical compositions for once daily administration that are suitable for the treatment of central nervous system ("CNS") diseases, including Alzheimer's disease. (9:44-58). The compositions of the invention contain memantine, or a pharmaceutically acceptable salt of memantine, and one or more pharmaceutically acceptable polymeric carriers (such as a coating and/or matrix) that modify the release of the memantine active ingredient. (Abstract, 3:13-23, 5:43-56, 6:49-53). The compositions sustain the release of the memantine

active ingredient "from at least about 70% to about 80% in about 4 hours to about 24 hours." (3:24-27). The specification describes preferred "6-hour" and "12-hour" formulations in which "at least 70%, preferably at least 80% of the active ingredient" is released after about 6 hours or after about 12 hours, respectively. (3:32-55, 6:31-48).

B. The Asserted Claims

For the '009 patent, claims 1-3 and 20-23 are asserted. Claim 1 is representative:

> A method for treating Alzheimer's disease comprising
>
> once daily administration of **a modified release solid oral dosage form** comprising
>
> 28 mg ±5% of memantine or a pharmaceutically acceptable salt thereof, and
>
> a pharmaceutically acceptable polymeric carrier **substantially contributing to the modification of the release** of the memantine or pharmaceutically acceptable salt thereof,
>
> said dosage form sustaining release of the memantine or pharmaceutically acceptable salt thereof from about 4 hours to about 24 hours following entry of said form into a use environment, wherein
>
> said dosage form has a single phase dissolution rate of less than about 80% after passage of about 6 hours following said entry into said use environment.

(Ex. A-1 at 22:9-21, emphasis added). The '009 claims are generally directed to methods for treating Alzheimer's disease. Memantine or a pharmaceutically acceptable salt is administered once daily in an amount of 28 mg ±5%. The memantine is in a modified release dosage form that includes a "polymeric carrier" that "substantially contribut[es] to the modification of the release" of the formulation. The claims also recite certain release characteristics of the formulation. For example, the formulation recited in claim 1 sustains release of the memantine from about 4 hours to about 24 hours following entry "into a use environment." The formulation also has a "single phase" dissolution rate of less than about 80% after passage of about 6 hours.

C. The Pertinent Art and the Person of Ordinary Skill in the Art

The pertinent art for the '009 patent is the field of pharmaceutical formulation. (*See* 1:14-19). The credentials and experience of a person of ordinary skill in the art for the '009 patent are comparable to the person of ordinary skill for the Went patents. (*See* Section V.D., *supra*).

D. The Disputed Claim Terms

The parties dispute the construction of two terms in the asserted '009 patent claims.

1. "a modified release solid oral dosage form"

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
1, 21, 22	a modified release solid oral dosage form	a solid oral dosage form that sustains the release of the active ingredient over an extended period of time as compared to an immediate release dosage form	a *single* solid oral dosage form that sustains the release of the active ingredient over an extended period of time as compared to an immediate release dosage form

The dispute regarding this term is whether the claims of the '009 patent should be limited to a single unit of the claimed modified release dosage form – *e.g.*, a single tablet or capsule – or whether the claims should be understood according to their plain language to refer to the total amount administered in each daily dosage. Plaintiffs' proposed construction tracks the claim language "solid oral dosage form" exactly. Defendants, by contrast, seek to read in the word "single," which does not appear in the claims, is not required by the intrinsic evidence, and therefore, should not be added.[16]

Indeed, Defendants' proposed construction actually conflicts with the specification, which fully supports Plaintiffs' proposal. In particular, the specification consistently

[16] The parties appear to agree on the construction of "modified release" in this term, based on the disclosure in the specification. (*See, e.g.*, 1:51-56, 9:66-10:3).

distinguishes between the "dosage form" of the drug product and the "strength" or the "tablet" embodiment of that "dosage form." For example, the specification states:

> ***In the 12-hour oral dosage form of the present invention***, the active ingredient is usually present in amounts from about 1.0% w/w to about 20.0% w/w, preferably from about 1.6% w/w to about 20.0% w/w, most preferably from about 2.5% w/w to about 20% w/w. ***Alternatively, the active ingredient may be measured as mg per tablet***, ranging from about 5 to about 80 mg per tablet. Preferably, the ***tablets*** contain 7 mg, 10 mg, 20 mg, 28 mg, 40 mg or 80 mg active ingredient.

(3:35-43 (emphases added).) The term "dosage form" relates to the extended release period of the drug product (here, 12 hours), while the strength of the drug product is described in terms of "tablets." There is no limitation on the number of tablets that can comprise a dosage form. Similarly, the specification states:

> Whereas for extended release tablets, as in the present invention, when the drug product ***is in the same dosage form but in a different strength***, and is proportionally similar in its active and inactive ingredients and has the same drug release mechanism, a lower strength can be granted a biowaiver if it exhibits similar dissolution profiles, f2>50, in three diverse pH buffers (between pH 1.2 and 7.5) by the recommended test method.

(12:4-11 (emphasis added).) Again, the specification expressly distinguishes between "dosage form" and "strength," and places no limit on the number of "strengths" or "tablets" that can comprise a "dosage form."

The examples disclosed in the specification are also fully consistent with Plaintiffs' construction. Example 1 states: "The following tables provide the exemplary makeup of ***modified release tablets*** including the active components, polymeric matrix, and other excipients for ***the specified dosage forms*** with specific target release time periods." (12:40-43, emphasis added). Notably, the tables identify two different "dosage forms" – a 12 hour formulation and a six hour formulation – with each "dosage form" shown at a number of different tablet strengths:

TABLE 1

	mg per tablet				% w/w			
	10 mg	20 mg	40 mg	80 mg	10 mg	20 mg	40 mg	80 mg
12 Hour Formulation STRENGTH:								
Memantine Hydrochloride	10	20	40	80	2.5%	5.0%	10.0%	18.1%
HPMC (Synchron KF)	306	306	306	306	76.5%	76.5%	76.5%	69.6%
Lactose	60	50	30	30	15.0%	12.5%	7.5%	6.9%
Fumed Silica (Cab-O-Sil)	4	4	4	4	1.0%	1.0%	1.0%	0.9%
Talc	16	16	16	16	4.0%	4.0%	4.0%	3.6%
Magnesium Stearate	4	4	4	4	1.0%	1.0%	1.0%	0.9%
Total	400	400	400	440	100.0%	100%	100.0%	100.0%
6 Hour Formulation STRENGTH:								
Memantine Hydrochloride	10	20	40	80	5.0%	10.0%	20.0%	33.3%
HPMC (Synchron KF)	130	130	130	130	65.0%	65.0%	65.0%	54.2%
Lactose	48	38	18	18	24.0%	19.0%	9.0%	7.5%
Fumed Silica (Cab-O-	2	2	2	2	1.0%	1.0%	1.0%	0.8%

(Table 1 at 12:44-67). Thus, Example 1 distinguishes explicitly between dosage forms and tablet strengths. (*See also* Example 4, disclosing 6 hour and 12 hour "release formulations" at 40 mg tablet strength).

Finally, during prosecution, the asserted claims were amended to require once daily administration of "28 mg ± 5%" of memantine. This amendment specified the total dosage amount, but did not limit the claims to a ***single*** unit – *i.e.*, a single tablet or capsule. (Ex. B-1, 3/18/2010, Final Office Action at 2-6, 6/2/2010, Response to Final Office Action at 2-8, 3/10/2011, Final Office Action at 2-10, 3/15/2011, Response to Final Office Action at 2-7). The modified release dosage form may be administered in multiple units once daily – such as two 14 mg capsules – that together, provide the claimed memantine dosage of 28 mg ± 5%. In sum, the intrinsic evidence supports Plaintiffs' proposed construction and is inconsistent with Defendants' attempt to add the limitation "single."

2. "substantially contributing to the modification of the release"

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
1, 21, 22	substantially contributing to the modification of the release	plain meaning; no construction necessary	Indefinite

The asserted claims of the '009 patent describe one of the ingredients in the modified release dosage form as a "polymeric carrier." ('009 patent, claims 1, 21, 22). The specification defines the claimed "polymeric carrier" as a pharmaceutically acceptable polymer, such as a coating or a matrix. (3:17-23, 5:49-56, 6:49-51). The polymeric carrier acts as a "release modifier" that is used to achieve the desired release rate of the memantine active ingredient. (5:49-56, 6:49-51). Specifically, the "polymeric carrier" in the claimed composition is described as "substantially contributing to the modification of the release" of memantine.

The parties dispute the meaning of "substantially" in this term. As set forth in Plaintiffs' proposal, no construction is necessary. As used in the phrase "substantially contributing to the modification of the release," the word "substantially" denotes "language of magnitude" because it describes how much the polymeric carrier "contribut[es] to the modification of the release." *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1333-34 (Fed. Cir. 2010). In the context of the asserted claims, "substantially" refers to a polymeric carrier that contributes a substantial amount to modifying the release of the memantine active ingredient, as opposed to a polymer that has little or no impact on the modification of the release. No construction of the term "substantially" is necessary beyond the plain and ordinary English-language meaning.

In contrast, Defendants contend that a person of ordinary skill in the art would not reasonably understand the meaning of this term, and therefore, it is indefinite. Notably, Defendants cite no intrinsic evidence in support of this contention. (Joint Claim Construction

Chart, D.I. 80 at 28). Instead, Defendants appear to argue that because the term "substantially" is a term of degree, rather than a numerical figure, it is indefinite.

Contrary to Defendants' argument, the Federal Circuit has repeatedly confirmed that terms of degree such as "substantially" do not prevent a person of skill in the art from ascertaining the scope of the claim when read in the context of the specification and prosecution history. *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349 (Fed. Cir. 2012) (the term "substantially planar" not indefinite). Indeed, terms of degree like "approach each other," "close to," "substantially equal," and "closely approximate" are "ubiquitous in patent claims." *Id*. at 1359. According to the Federal Circuit, "[s]uch usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts." *Id*. (citing *Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 821 (Fed. Cir. 1988)).

The Supreme Court's recent decision in *Nautilus*, 134 S. Ct. at 2129, does not change this result. Terms of degree, like other claim terms, must provide reasonably "objective boundaries" for those of skill in the art. *See DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014). But as the Supreme Court acknowledged in *Nautilus*, "absolute precision" in claim language is "unattainable." *Nautilus*, 134 S. Ct. at 2129.

Here, the claims, when read in light of the specification, inform those skilled in the art with reasonable certainty of the scope of the term "substantially." In the Background of the Invention, the specification explains that modified release solid oral dosage forms "permit the sustained release of the active ingredient over an extended period of time." (1:51-56). More specifically, for the claimed compositions, the specification discloses that the memantine active

ingredient is released at a rate of "from at least about 70% to about 80% in about 4 hours to about 24 hours." (3:24-27). The specification further describes preferred "6-hour" and "12-hour" formulations in which "at least 70%, preferably at least 80% of the active ingredient" is released after about 6 hours or after about 12 hours, respectively. (3:32-55, 6:31-48).[17] In contrast, the specification distinguishes immediate release solid dosage forms, which "permit the release of most or all of the active ingredient over a short period of time, such as 60 minutes or less." (1:56-59; *see also* 9:64-10:3).

Thus, the specification discloses what constitutes a substantial contribution to modifying the release of the claimed compositions. "Substantially contributing" to the modification of release in this context refers to a time scale of hours, or even days, for the claimed modified release compositions of the invention, as opposed to a time scale of minutes for an immediate release form. Read in light of the specification and the rest of the claim language, a person of ordinary skill would understand with reasonable certainty the boundaries for the term "substantially contributing" to the modified release of the claimed compositions. Defendants' contention that this term is indefinite should be rejected. The term "substantially" is used according to its plain meaning and requires no construction.

VII. CONCLUSION

For all the reasons discussed above, Plaintiffs respectfully request that the Court adopt their proposed constructions for the claim terms in dispute.

[17] This time scale for modified release – on the order of hours – is also reflected in the asserted claims. (*See, e.g.*, Ex. A-1 at claims 1 and 22 ("from about 4 hours to about 24 hours following entry of said form into a use environment"); claim 1 (single phase dissolution rate of "less than about 80% after passage of about 6 hours"); claims 20 and 21 (single phase dissolution rate of "about 30% to about 60% after about 2 to about 6 hours"); claims 22, 23 ("Tmax of more than 10 hours").

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CERTIFICATE OF SERVICE

I hereby certify that on March 27, 2015, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

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